

## REMARKS

### Status of the Claims

Claims 20-28 are pending in the above-identified application. No amendments are herein presented. Thus, no new matter has been added.

### Rejections under 35 U.S.C. § 103

The Examiner Rejects claims 20-28 under 35 U.S.C. § 103 as being unpatentable over Sakamoto (JP, Assignee Ajinomoto) in view of M. R. Johnson, Tanimoto, and Yalpani (the latter three of record).

Sakamoto is directed to a wetting agent “excellent in hygroscopicity and moisturizability”. (See attached translation of Sakamoto, page 1, col. 1, lines 10-11). Hygroscopic materials are defined as “readily taking up and retaining moisture.” (Webster’s Ninth New Collegiate Dictionary, pg 591, attached). The Sakamoto reference describes “hygroscopicity” as “the capability of absorbing of moisture, and moisturizability, i.e., the capability of inhibiting moisture evaporation.” (Translation, page 1, col. 2, lines 2-4).

Applicants submit that nothing in Sakamoto suggests that glutamate or polyglutamic acid would act as a sialogogue, i.e., an agent that stimulates the secretion of saliva. Instead the Sakamoto reference only refers to the ability to absorb moisture and inhibit its evaporation.

Furthermore, there is no indication from Johnson that polyglutamic acid itself acts as a sialogogue. The “pharmaceutically acceptable salts” of Johnson merely “retain or enhance the desired biological activity of the parent compound.” (Johnson, paragraph [0162]).<sup>1</sup> In comparison, if the primary active ingredient of Johnson had been an anti-diabetic agent, using the same quote and reasoning, the Examiner would not have come to the conclusion that the glutamic acid had any

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<sup>1</sup> Applicants note that the other Johnson publication, U.S. 2003/0199456 does not add anything to the analysis, and in fact uses the same language as the Examiner’s other Johnson reference. (See paragraphs [0179] and [011]).

significance to one of skill in the art whatsoever. In fact, reviewing Johnson, one of skill would fully expect that the experimental compounds of Johnson are required to be able to present any efficacy against an arbitrary disease.

Tanimoto is cited for the use of polyglutamic acid in food. (Office Action, page 6). Yalpani is cited for the size of polyglutamic acid in its varied forms, and the fact that it might be administered alone. (Office Action, page 7). However, neither Tanimoto or Yalpani would lead one of skill in the art to understand that polyglutamic acid would be effective in a therapy to treat xerostomia. Neither reference indicates that polyglutamic acid is a sialogogue, thus, neither reference remedies the deficiencies of Sakamoto and Johnson.

Accordingly, Applicants submit that one of skill, reading Sakamoto (JP, Assignee Ajinomoto) in view of M. R. Johnson, Tanimoto, and Yalpani would not find the present inventive method of treatment obvious. Applicants respectfully request that the rejection be withdrawn.

### **CONCLUSION**

Applicants respectfully request reconsideration and withdrawal of the outstanding rejections, and suggest that the claims are in a condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Mary M.H. Eliason, Reg. No. 58,303 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

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Applicants submit that therefore, the addition of this reference does not provide any additional reason for one of skill to expect pharmaceutical activity in xerostomia from polyglutamic acid.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

By 

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Attachments: Sakamoto Translation

Excerpt from Webster's Dictionary, page 591

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(Total 4 pages)

## (54) WETTING AGENT

(21) Application number: Sho 58-75562  
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## SPECIFICATION

1. Title of the Invention WETTING AGENT

## 2. CLAIMS

A wetting agent comprising a water-soluble polyglutamate.

## 3. DETAILED EXPLANATION OF THE INVENTION

This invention relates to a wetting agent containing a water-soluble polyglutamate and has for its object the provision of a wetting agent that is high in safety and excellent in hygroscopicity and moisturizability.

In general, materials having high hygroscopicity have been used as a wetting agent in products whose quality is degraded when moisture is lost therefrom, e.g. cosmetics, ointments and confectionary and also in products used for the purpose of imparting humidity, e.g. skin lotions, creams, shoe creams and the like. There are quite many kinds of organic or inorganic materials having high hygroscopic power. However, usable wetting agents are limited in kind because of the necessity of their low influence on safety or shape stability of product.

Moreover, the properties that wetting agent should have are hygroscopicity, i.e., the capability of absorbing of moisture, and moisturizability, i.e., the capability of inhibiting moisture evaporation. In most cases, ordinarily wetting agents are used in combination so as to ensure these characteristics as necessary. However, among ordinarily used wetting agents, materials having great hygroscopicity, such as sodium lactate, PCA Na and the like are electrolytic in nature and thus, have unfavorable properties from the standpoint of formulation in products, thereby placing limitation on the amount of use and purpose. On the other hand, although polyol wetting agents such as glycerine, sorbitol, propylene glycol and the like have relatively good moisturizability. However, they are liable to bring about stickiness of products and thus, a difficulty is involved in a feeling in use upon application to cosmetics and the like. In addition, attention has been recently paid to hyaluronic acid for use as a wetting agent that has appreciable degrees of hygroscopicity and moisturizability and is good at use feeling. Starting materials therefor are rare types of natural matters such as cock's comb, human umbilical cord and the like and are thus expensive, so that their application is limited themselves.

The inventor made efforts so as to develop a wetting agent that has appreciable hygroscopicity and moisturizability and exhibits a good feeling in use and, as a result, found out excellent characteristic properties of a polyglutamate which is more inexpensive than hyaluronic acid, thereby arriving at completion of the invention.

The polyglutamic acid used as a wetting agent of the present invention may be either synthetic polyglutamic acid derived from a polymer of glutamic acid ester-N-carboxylic anhydride, or natural polyglutamic acid obtained from a number of strains as a fermentation product. For salts, there are used salts of alkali metals such as sodium, potassium, lithium and the like, and water-soluble salts such as ammonium salt, ethanolamine salt, diethanolamine salt, triethanolamine salt, basic amino acid salt and the like. The polyglutamate is a polybasic salt. The neutrality of the salt used in the invention may be arbitrarily selected within a pH range of 3 to 10 in the form of an aqueous solution depending on the purpose.

The degree of polymerization of the polyglutamate of the invention ranges 10 to 1000 and one having a polymerization degree within a range of 20 to 100 is more excellent from the standpoint of the hygroscopicity and moisturizability.

(NMF) of skin, its use as a wetting agent for cosmetics not only keeps the form of product, but also brings about such effects that an appropriate degree of moist feeling and smoothness are imparted to the skin after use and the skin is prevented from chapping.

As such cosmetics include hair spray, styling spritz, cleansing cream, skin lotion, shampoo, rinse, hair treatment, milky lotion, lotion, shaving cream, cold cream, hand cream, permanent wave lotion, solid detergent, liquid detergent, perspiration deodorant and the like, and the agent is applicable irrespective of the form of product. Where the wetting agent of the present invention is added to a variety of products, a degree of wettability corresponding to the added amount can be imparted. In this connection, if the agent is generally used in the range of 0.01 to 10 wt%, preferably 0.005 to 5 wt%, a desired purpose can be attained.

Further, when the wetting agent of the invention is used in combination with other types of wetting agents, e.g. glycerine, propylene glycol, sorbitol, sodium PCA, sodium lactate, an amino acid and the like, its effect is not impeded. If necessary, various types of surface active agents, solubilizers and oils may be used in combination.

As shown in examples appearing hereinafter, the wetting agent of the present invention exhibits excellent hygroscopicity and moisturizability, and imparts a nonstick, moist feel to a matter to be applied owing to the film formability resulting from the polymer structure.

Accordingly, the wetting agent of the present invention added to products that have a tendency of losing moisture upon exposure to air, e.g. shoe creams, paints, paper articles and the like, serves to maintain and improve the quality thereof.

Moreover, when the wetting agent is added to products that are unwilling to become electrically charged, such as fiber products, copying papers, records and the like, or the products is subjected to immersion treatment, such as immersion in an aqueous solution of the wetting agent of the present invention. The product is imparted with an appropriate degree of hygroscopicity, and especially, fiber products having subjected to such a treatment is enhanced in moist feeling and improved in texture.

Hence, the wetting agent of the present invention is effective for a wide variety of products and is particularly made of a material of high safety, for which it can be added to foods, cosmetics and the like. Especially, since a polyglutamate is a kind of polypeptide that is a natural moisturizing factor

The invention is particularly described by way of examples.

#### Example 1

The hygroscopicity and moisturizability of 10% aqueous solutions of the wetting agent of the invention and wetting agents for reference were measured according to a wide-line pulse NMR method in terms of an amount of unfrozen water per unit dry weight of wetting agent at -20°C. (Fragrance Journal, 10(5), 59(1982)). As is apparent from Table 1, the hygroscopicity and moisturizability of the polyglutamate is at a level comparable to those of the wetting agents such as glycerine, Na pyrrolidone carboxylate (PCA) and the like, and those salts having relatively low molecular weights are better and the hygroscopicity and moisturizability in the vicinity of weak acidity (at a pH of about 5) is excellent.

Table 1

Amount of unfrozen water of a 10% aqueous solution of individual wetting agent at -20°C (wide-line pulse NMR method)  
(average value in the range of -30°C to -10°C in the course of thawing)

Wetting agent				Amount of unfrozen water (g of H <sub>2</sub> O/g dry weight)
Invention	Synthetic sodium polyglutamate	Molecular weight	pH	
		30	3.0	1.20
			5.7	1.58
			10.0	1.33
		300	5.8	1.16
			10.0	0.87
	Fermented sodium polyglutamate	300	5.0	1.19
			8.0	0.95
Reference	Sorbitol			0.55
	Glycerine			1.47
	Sodium PCA			1.62
	Sodium lactate			2.21

The oil phase and aqueous phase were, respectively, heated to 80°C, and the aqueous phase was gradually added to the oil phase under agitation, followed by agitation until the temperature was down to 40°C and cooling to obtain a milk lotion.

30 adult females were divided into two groups, which made use of the above formulation product and a reference product obtained by removing the wetting ingredient from the above formulation, respectively. As a result, such an evaluation that a feel in use and feeling after use were good as being moist was obtained from the group making use of the formulation product of the invention, whereas a tendency that the skin became dry was observed for the group making use of the wetting agent-free product.

#### Example 4 Hair shampoo

A hair shampoo having the following formulation was prepared.

coconut oil fatty acid acylglutamic acid/triethanolamine salt (30%)	30.0 g
sodium lauryl ether sulfate (25%)	20.0 g
coconut oil fatty acid diethanolamide	3.0
disodium citrate 1.5 hydrate	2.0
polyethylene glycol monostearate	1.0
propylene glycol	3.0

#### Example 2

3 g of a 1% aqueous solution of each of a wetting agent of the invention and reference agents was placed in a thermostatic bath at 25°C, under which air having a relative humidity of 25% was introduced into the bath at a rate of 10 liters/minute.

Moisturizability was checked from a weight loss ascribed to the evaporation of water. The results are as shown in Fig. 1, revealing that the wetting agent of the invention exhibits moisturizability at a level equal to those of sodium PGA and hyaluronic acid.

#### Example 3 Milk lotion

A milk lotion having the following formulation was prepared according to a procedure set out below.

Oil phase	liquid paraffin	31.6 g
	solid paraffin	4.5 g
	cetanol	4.5 g
	sorbitan monostearate	1.8 g
	polyoxyethylene (20) sorbitan monoolcate	2.8 g
Aqueous phase	Na polyglutamate (degree of polymerization of 30)	1.0 g
		1.0 g
	sodium PCA	1.0 g
	water	50.0 g
	preservative	0.1 g

sodium polyglutamate (degree of polymerization of 300)	1.0
polyoxyethylene lanolin alcohol	2.0
water	38.0

This shampoo was imparted with moistness to the hair after rinsing and was better in texture than a wetting agent-free product.

#### Example 5 Coating of bean-jam bun

A composition was prepared according to the following formulation.

Wheat flour	100 g
Baking powder	5 g
White sugar	60 g
Water	3 tablespoons

Water and white sugar were combined and heated, and were allowed to cool after dissolution, followed by further addition of wheat flour and baking powder and well mixing. This composition was divided into halves. One was admixed with 1% of sodium polyglutamate (degree of polymerization of 300) and 1% of sodium lactate.

Both compositions were steamed to make coatings of a bean-jam bun. Both were exposed to air at room temperature for 10 days, whereupon little change was recognized for the coating to which the

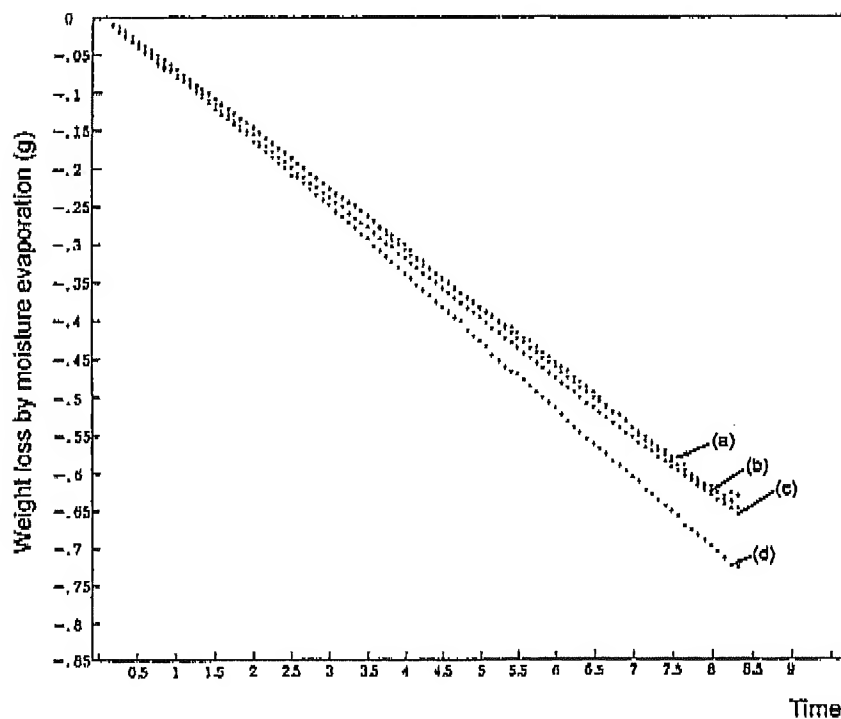
wetting agent of the invention had been added, and the agent-free coating lost moisture therefrom and became dried.

#### 4. BRIEF DESCRIPTION OF THE DRAWING

Fig. 1 is a graph showing a weight loss owing to the evaporation of moisture in relation to time when 1% aqueous solution of each wetting agent was placed in a thermostatic bath at 25°C, under which air having a relative humidity of 25% was introduced into the bath. Incidentally, in the drawing, reference character (a) is the measurement result only used Na pyrrolidone carboxylate; (b) is only hyaluronic acid; (c) is only sodium polyglutamate (degree of polymerization of 300) of the invention; and (d) is only water, respectively.

Applicant: Ajinomoto Co., Inc.

Table 1



# Ninth New Collegiate Dictionary

*A Merriam-Webster®*

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hy-la 'hi-la\ n [NL, fr. Gk *hylē*] (1842) : any of a genus (*Hyala*) of true frogs

hy-lo-zo-ism 'hi-lə-'zō-'iz-əm\ n [Gk *hylē* + *zōōs* alive, living; akin to Gk *zōō* life — more at QUICK] (1678) : a doctrine held esp. by early Gk philosophers that all matter has life — hy-lo-zo-ist 'zō-'əst-ən\ n — hy-lo-zo-ist-ic 'zō-'is-tik\ adj

hy-men 'hi-mən\ n [LL, fr. Gk *hymēn* membrane] (1615) : a fold of mucous membrane partly closing the orifice of the vagina — hy-men-al 'hi-mən-'l\ adj

Hymen n [fr. Gk *Hymēn*] : the Greek god of marriage

hy-me-ne-al 'hi-mə-'nē-əl\ adj [L *hymenaeus* wedding song, wedding, fr. Gk *hymenaios*, fr. *Hymēn*] (1602) : NUPTIAL — hy-me-neal-ly 'nē-'ə-lē\ adv

hymeneal n (1655) 1 *pl. archaic* : NUPTIALS 2 *archaic* : a wedding hymn

hy-me-ni-um 'hi-'mē-'nē-əm\ n, *pl. -nia* \-'nē-ə\ or -ni-ums [NL, fr. Gk *hymēn*] (1830) : a spore-bearing layer in fungi consisting of a group of asci or basidia often interspersed with sterile structures

hy-me-nop-ter-an 'hi-mə-'nāp-tə-'rən\ n [NL *Hymenoptera*, fr. Gk, neut. *pl. of hymenopteros* membrane-winged, fr. *hymēn* + *pteron* wing — *pteron* + *ptēr* 'FEATHER] (ca. 1842) : any of an order (Hymenoptera) of highly specialized insects with complete metamorphosis that include the bees, wasps, ants, ichneumonids, sawflies, gall wasps, and related forms, often associate in large colonies with complex social organization, and have usu. four membranous wings and the abdomen generally borne on a slender pedicel — hymenopter-an *adj* — hy-me-nop-ter-ous 'v-rəs\ adj

hy-me-nop-ter-on \-'tə-,rən-,-'rən\ n, *pl. -tera* \-'tə- also -ter-ons [NL, fr. Gk, neut. of *hymenopteros*] (1877) : HYMEOPTERAN

hymn 'him\ n [ME *ymne*, fr. OE *ymen*, fr. L *hymnus* song of praise, fr. Gk *hymnos*] (bef. 12c) 1 *a* : a song of praise to God 2 *a* : a metrical composition adapted for singing in a religious service 2 : a song of praise or joy 3 : something resembling a hymn : PAEAN

hymn vb hymned 'himd\; hymning 'him-ŋ\ v (1667) : to praise or worship in or as if in hymns ~ vi : to sing a hymn

hym-nal 'him-nəl\ n [ME *hymnale*, fr. ML, fr. L *hymnus*] (15c) : a collection of church hymns

hym-na-ry 'him-nə-rē\ n, *pl. -ries* (1888) : HYMNAL

hymn-book 'him-'būk\ n (1779) : HYMNAL

hymn-ody 'him-nəd-'ē\ n [LL *hymnodia*, fr. Gk *hymnōidia*, fr. *hymnos* + *ōidē* to sing — more at ATONE] (1711) 1 hymn singing 2 : hymn writing 3 : the hymns of a time, place, or church

hymn-ol-ogy 'him-'nāl-'ə-jē\ n [Gk *hymnologia* singing of hymns, fr. *hymnos* + *-logia* -logy] (1638) 1 : HYMNODY 2 : the study of hymns

hy-oid 'hi-'ōid\ adj [NL *hyoides* hyoid bone] (1842) : of or relating to the hyoid bone

hyoid bone n [NL *hyoides*, fr. Gk *hypooidēs* shaped like the letter epsilon (Υ, υ), being the hyoid bone, fr. *y*, *hy* upslon] (ca. 1811) : a bone or complex of bones situated at the base of the tongue and supporting the tongue and its muscles

hy-o-scine 'hi-'ə-,sēn\ n [ISV *hyosciamine* + *-ine*] (1872) : SCOPOLAMINE; *esp.* : the levorotatory form of scopolamine

hy-o-sey-a-mine 'hi-'ə-'si-'ə-,mēn\ n [G *hyosciamin*, fr. NL *Hyoscyamus*, genus of herbs, fr. L *henbane*, fr. Gk *hyoskamos*, lit., swine's bean, fr. *hyos* (gen. of *hys* swine) + *kyamos* bean — more at SOW] (1858) : a poisonous crystalline alkaloid  $C_{17}H_{23}NO_3$  of which atropine is a racemic mixture; *esp.* : its levorotatory form found esp. in the plants *belladonna* and *henbane* and used similarly to atropine

hyp- see HYPO-

hyp-abys-sal 'hip-'ə-bis-əl, 'hi-pə-'əd\ [ISV] (1895) : of or relating to a fine-grained igneous rock usually at a moderate distance below the surface — hyp-abys-sal-ly \-'ə-lē\ adv

hyp-ae-thral 'hi-'pē-'thrəl\ adj [L *hypaethrus* exposed to the open air, fr. Gk *hypoathros*, fr. *hypo-* + *athēr* ether, air — more at ETHER] (1794) 1 : having a roofless central space (~ temple) 2 : open to the sky 3 : OUTDOOR

hyp-an-thi-um 'hi-'pan-(ə-)thē-əm\ n, *pl. -thia* \-'thē-ə\ [NL, fr. *hypo-* + *anth-* + *-ium*] (ca. 1855) : an enlargement of the floral receptacle bearing on its rim the stamens, petals, and sepals and often enlarging and surrounding the fruits (as in the rose hip) — hyp-an-thi-al 'v-thē-əl\ adj

hype 'hip\ v *hyped*; *hyping* (1926) 1 : PUT ON, DECEIVE 2 *a* : STIMULATE, ENLIVEN — *usu.* used with *up* b : INCREASE (gimmicks designed to ~ attendance at the games) 3 : to promote or publicize extravagantly — *hyped-up* 'hip-'əd\ adj

hype [by shortening & alter.] (ca. 1936) 1 slang : HYPODERMIC 2 slang : a narcotics addict 3 : DECEPTION, PUT-ON 4 : extravagant promotion or advertising

hyp-er 'hi-pər\ adj [short for *hyperactive*] (1971) : HIGH-STRUNG, EXCITABLE

hyper- prefix [ME *iper*, fr. L *hyper*, fr. Gk, fr. *hyper* — more at OVER] 1 : above : beyond : SUPER- (hyperphysical) 2 *a* : excessively (hyper-sensitive) b : excessive (hypermaria) 3 : that is or exists in a space of more than three dimensions (hypercube) (hyperspace)

hyper-acuity	hyper-con-cent-ra-tion	hyper-ex-cited
hyper-acute	hyper-con-sci-ent-i-ous	hyper-ex-cite-ment
hyper-ag-gres-sive	hyper-con-sci-ent-i-ous-ness	hyper-ex-cre-tion
hyper-alert	hyper-con-sci-ous	hyper-fas-tid-i-ous
hyper-arid	hyper-con-sci-ous-ness	hyper-fem-i-nine
hyper-arousal	hyper-de-vel-op-ment	hyper-function
hyper-aware	hyper-de-vel-op-ment	hyper-functional
hyper-aware-ness	hyper-e-mo-tion-al	hyper-function-ing
hyper-boom	hyper-e-mo-tion-al-ity	hyper-im-mu-ni-za-tion
hyper-ca-tab-ol-ism	hyper-e-mo-tion-al-ly	hyper-im-mu-nize
hyper-cau-tious	hyper-en-er-getic	hyper-in-fla-tion-ary
hyper-civ-il-ized	hyper-ex-cit-a-bil-ity	hyper-in-nerv-a-tion
hyper-co-agu-la-bil-ity	hyper-ex-cit-a-bil-ity	hyper-in-tel-lec-tual
hyper-co-agu-la-bil-ity	hyper-ex-cit-a-bil-ity	

\ə\ abut    \ə\ kitten, F table    \ər\ further    \a\ ash    \ā\ ace    \ä\ cot; cart  
 \aʊ\ out    \ch\ chin    \e\ bet    \ē\ easy    \g\ go    \i\ hit    \ī\ ice    \j\ job  
 \j\ sing    \ō\ go    \ó\ law    \ói\ boy    \th\ thin    \th\ the    \ü\ loot    \ú\ foot  
 \y\ yet    \zh\ vision    \á, k, ñ, œ, ue, ŷ, see Guide to Pronunciation